

Cholesterol pill could raise cancer risk, warn scientists



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Caution: Heart experts have warned against using the cholesterol drug Inegy

A drug used to treat high cholesterol could cause cancer, doctors warned last night.

Heart experts called for caution over the use of Inegy, which is taken as a daily pill.

At least one leading specialist said he would not take the drug, while others said the jury was still out.

The U.S. has ordered an investigation into Inegy, which combines the widely used statin drug simvastatin with a new medication called ezetimibe.

While statins block cholesterol in the liver, ezetimibe blocks the absorption of cholesterol in the gut.

In Britain, about 300,000 NHS prescriptions have been dispensed for Inegy in the last two years. Other patients use ezetimibe on its own.

NICE, the NHS 'rationing' body, last November approved wider use of ezetimibe for the treatment of hypercholesterolaemia, a condition leading to high concentrations of cholesterol in the blood.

Results from a controversial study published yesterday in the New England Journal of Medicine show a higher than expected number of cancer cases reported among patients taking Inegy.

It showed a total of 105 cancer cases among Inegy patients compared with 70 taking a placebo. That was an increase on the preliminary rates of 93 and 65 respectively reported in July.

The trial found no benefit of the drug in reducing aortic disease in patients with a partially blocked heart valve, and little effect on cardiovascular events such as heart attacks.

The journal also noted that ezetimibe interfered with the gastrointestinal absorption not only of cholesterol but also other molecules that could conceivably affect the growth of cancer cells.

Lead investigator Terje Pedersen, of Ullevål University Hospital in Oslo, said cross-checks with cancer rates in two much larger ongoing trials did not support the idea that Inegy was linked to cancer.

There was no evidence for a cancer-causing mechanism, he told the European Society of Cardiology congress in Munich.

But Professor Heinz Drexel, of the University of Innsbruck in Austria and spokesman for the European Society of Cardiology, said: 'I am not sure that the efficacy is proven and I am not sure that the safety is proven. I wouldn't take the drug myself.'

'In patients with an urgent need to reduce cholesterol I would give them the drug, but they are the exception and that is not consistent with how it is being used currently.'

'It is being more widely used than I think it should be. We can use something else in patients whose cholesterol is not sky-high.'

An investigation by Oxford University researchers suggested that the higher rate of cancers could be a 'chance' finding, or a statistical fluke.

But Professor Drexel said the size of the increase suggested it was not chance, although he accepted it did not prove the drug caused cancer.

A longer follow-up will be needed to know for certain, he added.

Dr Mike Knapton, director of prevention and care at the British Heart Foundation, said: 'There is no suggestion that statins increase the risk of cancer.'

'The combined evidence of all data on cancer and ezetimibe in combination with a statin shows no increased risk of developing cancer.'

'The data from the big trials are encouraging but the evidence is not yet conclusive, because many of the patients studied have been followed up for a relatively short period of time so far.'

'Because one study did show a cancer risk, it is crucial that others continue and are monitored closely to definitively confirm or refute any link.'

'People should be reassured that drug regulators will act quickly if robust evidence of risk to patient health appears.'

'If you have been prescribed ezetimibe, you should continue to take it. If you have concerns about side-effects of this or other medication, you should talk to your doctor to weigh up the risks and benefits.'

A spokesman for Merck and Schering-Plough, makers of Inegy, said: 'We believe that the cancer findings in the study are likely to be an anomaly and that in light of all the available data, it does not support an association with Inegy.'

'We are working with regulatory agencies to further evaluate the data. However, we do not believe that changes in the clinical use of Inegy are warranted.'

While 300,000 NHS prescriptions have been dispensed for the drug in the last two years, experts say many of those are likely to be repeat prescriptions for patients who go back for more after a break or need their supply to be topped up.

The actual numbers of those taking the drug in Britain is likely to be in the tens of thousands.